contains 0.13 to 0.5 percent aluminum acetate).

(b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).

(c) Witch hazel.

[58 FR 54462, Oct. 21, 1993, as amended at 59 FR 28768, June 3, 1994]

§ 347.50 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''astringent.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications'' any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing aluminum acetate identified in § 347.10(a).* ''For temporary relief of minor skin irritations due to'' (select one or more of the following: ''poison ivy,'' ''poison oak,'' ''poison sumac,'' ''insect bites,'' ''athlete's foot,'' or ''rashes caused by soaps, detergents, cosmetics, or jewelry'').

(2) *For products containing aluminum sulfate identified in § 347.10(b) for use as a styptic pencil.* ''Stops bleeding caused by minor surface cuts and abrasions as may occur during shaving.''

(3) *For products containing witch hazel identified in § 347.10(c).* (i) ''For relief of minor skin irritations due to'' (select one or more of the following: ''insect bites,'' ''minor cuts,'' or ''minor scrapes'').

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''For external use only. Avoid contact with the eyes.''

(2) *For products containing aluminum acetate identified in § 347.10(a) or witch hazel identified in § 347.10(c).* ''If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a'' (select one of the following: ''physician'' or ''doctor'').

(3) *For products containing aluminum acetate identified in § 347.10(a) used as a compress or wet dressing.* ''Do not cover compress or wet dressing with plastic to prevent evaporation.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing aluminum acetate identified in § 347.10(a)*—(i) *For products used as a soak.* ''For use as a soak: Soak affected area in the solution for 15 to 30 minutes. Discard solution after each use. Repeat 3 times a day.''

(ii) *For products used as a compress or wet dressing.* ''For use as a compress or wet dressing: saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Discard solution after each use. Repeat as often as necessary.''

(2) *For products containing aluminum sulfate identified in § 347.10(b) for use as a styptic pencil.* ''Moisten tip of pencil with water and apply to the affected area. Dry pencil after use.''

(3) *For products containing witch hazel identified in § 347.10(c).* ''Apply to the affected area as often as necessary.''

[58 FR 54462, Oct. 21, 1993, as amended at 59 FR 28768, June 3, 1994]

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

SOURCE: 57 FR 27656, June 19, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 348.1 Scope.

(a) An over-the-counter external analgesic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 348.3 Definitions.

As used in this part:

(a) *Male genital desensitizing drug product.* A drug product applied to the penis to help in temporarily slowing the onset of ejaculation.

(b) [Reserved]

Subpart B—Active Ingredients

§ 348.10 Analgesic, anesthetic, and antipruritic active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) *Male genital desensitizers.* (1) Benzocaine, 3 to 7.5 percent in a water-soluble base.

(2) Lidocaine in a metered spray with approximately 10 milligrams per spray.

(b) [Reserved]

Subpart C—Labeling

§ 348.50 Labeling of external analgesic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as follows:

(1) *For products containing any ingredient identified in § 348.10(a).* ''Male genital desensitizer.''

(2) [Reserved]

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' any of the phrases listed in paragraph (b) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing any ingredient identified in § 348.10(a).* (i) ''Helps in the prevention of premature ejaculation.''

(ii) ''For temporary male genital desensitization, helping to slow the onset of ejaculation.''

(iii) ''Helps in temporarily'' (select one of the following: ''retarding the onset of,'' ''slowing the onset of,'' or ''prolonging the time until'') followed by ''ejaculation.''

(iv) ''For reducing oversensitivity in the male in advance of intercourse.''

(2) [Reserved]

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) *For products containing any ingredient identified in § 348.10(a).* (i) ''Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a doctor.''

(ii) ''Avoid contact with the eyes.''

(iii) ''If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist, consult a doctor.''

(2) [Reserved]

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing any ingredient identified in §348.10(a)*—(i) *For products containing benzocaine identified in §348.10(a)(1).* ''Apply a small amount to head and shaft of penis before intercourse, or use as directed by a doctor. Wash product off after intercourse.''

(ii) *For products containing lidocaine identified in §348.10(a)(2).* ''Apply 3 or more sprays, not to exceed 10, to head and shaft of penis before intercourse, or use as directed by a doctor. Wash product off after intercourse.''

(2) [Reserved]

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

SOURCE: 53 FR 7090, Mar. 4, 1988, unless otherwise noted.

Subpart A—General Provisions

§349.1 Scope.

(a) An over-the-counter ophthalmic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in §330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§349.3 Definitions.

As used in this part:

(a) *Ophthalmic drug product.* A drug product, which should be sterile in accordance with §200.50, to be applied to the eyelid or instilled in the eye.

(b) *Astringent.* A locally acting pharmacologic agent which, by precipitating protein, helps to clear mucus from the outer surface of the eye.

(c) *Buffering agent.* A substance which stabilizes the pH of solutions against changes produced by introduction of acids or bases from such sources as drugs, body fluids, tears, etc.

(d) *Demulcent.* An agent, usually a water-soluble polymer, which is applied topically to the eye to protect and lubricate mucous membrane surfaces and relieve dryness and irritation.

(e) *Emollient.* An agent, usually a fat or oil, which is applied locally to eyelids to protect or soften tissues and to prevent drying and cracking.

(f) *Eyewash, eye lotion, irrigating solution.* A sterile aqueous solution intended for washing, bathing, or flushing the eye.

(g) *Hypertonicity agent.* An agent which exerts an osmotic gradient greater than that present in body tissues and fluids, so that water is drawn from the body tissues and fluids across semipermeable membranes. Applied topically to the eye, a hypertonicity agent creates an osmotic gradient which draws water out of the cornea.

(h) *Isotonicity.* A state or quality in which the osmotic pressure in two fluids is equal.

(i) *Vasoconstrictor.* A pharmacologic agent which, when applied topically to the mucous membranes of the eye,